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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RYCKMAN, MELISSA K

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/776,682	Applicant(s) MORALES ET AL.	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-58 is/are pending in the application.
- 4a) Of the above claim(s) 49-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/5/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to arguments filed 10/5/09.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-41 and 43-48 recites the limitation "the clips" in line 7 of claim 1.

There is insufficient antecedent basis for this limitation in the claim. It is unclear if each clip comprises two tissue-piercing legs, or if one clip is one tissue-piercing leg and the other clip is the other tissue-piercing leg. If the applicant intends each clip has two tissue-piercing legs, then line 8 with a tether passing though the loop, should be loops.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (U.S. Patent No. 5984933), and further in view of Friedman (WO 02/053011 A2).

Claim 37: Yoon teaches a device for applying at least one clip to annular tissue of a heart valve (capable of being used to clip annular tissue of a heart) the device comprising; a shaft having a proximal end and a distal end (Fig. 48); and at least one

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actuator (2460) at or near the proximal end of the shaft for causing the device to advance the tethered clip assembly from the shaft (Fig. 49), wherein the tethered clip assembly has a first deployed configuration and a second deployed configuration, the tethered clip assembly in the first deployed configuration comprising at least two clips separated by a greater distance than when in the second configuration, the tether is under longitudinal tension and the first distance is reduced (this configuration is capable of occurring during a variety of delivery option).

Yoon teaches the claimed invention including the clips being in the same position in both the first and second configuration but does not teach the clips comprise two tissue-piercing legs joined by a loop with the tether passing through the loop transversely to the legs, and the two clips are in a closed tissue-piercing position when the tethered clip assembly is in both its first and second deployed configuration.

However Friedman teaches a clip with two tissue-piercing legs (106, Fig. 12) legs joined by a loop with the tether passing through the loop transversely to the legs. It would have been obvious to one of ordinary skill in the art to use the clip of Friedman with the delivery device of Yoon, as piercing the tissue is advantageous for several types of surgery to further secure the tissue. Friedman teaches the two clips are in a closed tissue-piercing position when the tethered clip assembly is in both its first and second deployed configuration (page. 11, ll. 10, before withdrawal of the suture gun the clip is positioned as shown in Fig. 13).

Claims 38-40: Yoon teaches the device further comprises a clip crimping member (distal portion of 2440, Fig. 28), a plurality of clips (Fig. 48), each plurality of clips is couple to the tether (Fig. 48).

Claim 41: Yoon teaches at least one clip is T-shaped (see Fig. 44, if 2241 plane is shown, a T is formed out of 2240 and 2241).

Claims 42 and 43: Yoon teaches each of the plurality of clips includes two eyelets (2228), and the tether (2218a and 2218) has parallel segments passing through both eyelets of each clip (Fig. 44).

Claim 44: Yoon teaches a system for applying at least one clip to annular tissue of a heart valve, comprising: the device as claimed above in claim 37; and a stabilization device to capture and immobilize the annular tissue relative to the remainder of the heart (2232, Fig. 44, this inner face of the clip immobilizes the tissue).

Claims 45,46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (U.S. Patent No. 5984933) and Friedman (WO 02/053011 A2), as applied to claim 37 above, in view of Crowley (U.S. Patent No. 5524630).

Regarding claim 45 and 46 Yoon and Friedman disclose the claimed invention except for a visualization device adapted to directly view a valve annulus in a heart chamber and a visualization device comprising an ultrasonic imaging transducer. However, Crowley teaches a visualization device adapted to directly view a valve annulus in a heart chamber (Fig. 30) and a visualization device comprising an ultrasonic imaging transducer (Fig. 3 and 4).

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It would have been obvious to one of ordinary skill in the art to include a visualization device of Crowley at the end of the claimed invention to insure proper installation of the clips during surgery.

Regarding claim 48 Yoon and Friedman discloses the claimed invention except for a transparent element comprising a transparent balloon inflatable with a transparent inflation medium, however Crowley teaches a transparent balloon inflatable with a transparent inflation medium (col.4 ll.35, col. 17 ll. 6). It would have been obvious to one of ordinary skill in the art to include the balloon of Crowley at the end of the element to occlude blood flow, as this is common within the art.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (U.S. Patent No. 5984933), Friedman (WO 02/053011 A2) and Crowley (U.S. Patent No. 5524630) as applied to claim 45 above, further in view of Johnson (5766240).

Regarding claim 47 Yoon, Friedman and Crowley discloses the claimed invention except for an optical viewing element, however Johnson discloses an optical viewing element (col. 15 ll.44) disposed in a transparent element (col. 5 ll. 11). It would have been obvious to one of ordinary skill in the art to include an optical viewing element of Johnson to insure proper installation of the clips during surgery.

Double Patenting

The examiner acknowledges the receipt of the terminal disclaimer regarding U.S. Patent No. 6,986,775, however at this time the office has neither approved or denied the disclaimer, so the rejection will be maintained until it is resolved. At this time it is not necessary for the applicant to send another terminal disclaimer.

Claims 37-41 and 43-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,986,775. Although the conflicting claims are not identical, they are not patentably distinct from each other because '775 teaches all elements of the current application.

Claims 37-41 and 43-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-100 of copending Application No. 11/237,461. Although the conflicting claims are not identical, they are not patentably distinct from each other because all elements of the current application are claimed in application '461.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 37-41 and 43-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-46 of copending Application No. 12/131,840. Although the conflicting claims are not identical, they are not patentably distinct from each other because all elements of the current application are claimed in application '840.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 37-41 and 43-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 58-94 of copending Application No. 12/132,375. Although the conflicting claims are not identical, they are not patentably distinct from each other because all elements of the current application are claimed in application '375.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

/Melissa Ryckman/
Examiner, Art Unit 3773

/Melanie Tyson/
Examiner, Art Unit 3773
April 12, 2010